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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,988	01/29/2002	Zhihao Yang	83965HEC	6122

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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/059,988

Applicant(s)

Yang

Examiner

Arun Chakrabarti

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Jun 18, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 0603 6) ☒ Other: Detailed Action

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## DETAILED ACTION

### *Specification*

1. Claims 1 and 8 have been amended. No new claims have been added. Claims 1-14 are pending in this application.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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3. Claims 1-14 are rejected under 35 U.S.C. 103 (a) over Gilmanishin et al. (U.S. Patent 6,263,286 B1) (July 17, 2001) in view of Cubicciotti (U.S. Patent 6,287,765 B1) (September 11, 2001).

Gilmanishin et al teach a method for single molecule identification of a target DNA molecule in a random coil state (Abstract, Column 26, lines 45 to column 27, line 10 and Figures 8-9) comprising the following steps:

a) attaching an optically distinguishable material to a DNA sequence recognition unit (Column 25, lines 35-54);

b) hybridizing the DNA sequence recognition unit to the target DNA molecule in a random coil state to form a hybridized DNA complex in a random coil state (Column 19, lines 42-63);

c) stretching the hybridized DNA complex in a random coil state to form a hybridized DNA complex in a substantially linear configuration (Column 26, lines 45 to column 27, line 10 and Figures 8-9); and

d) detecting the optically distinguishable material in a sequential manner along the substantially linear hybridized DNA complex, thereby identifying the target DNA molecule (Examples 2-3 and Figure 9).

Gilmanishin et al teach a method wherein the optically distinguishable material comprises colored microparticles having different shapes ( Column 25, line 18 to column 26, line 37 and figure 8).

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Gilmanshin et al teach a method, wherein the colored microparticles comprise dye or nanocrystals (column 16, lines 38-50).

Gilmanshin et al teach a method, wherein the DNA sequence recognition unit comprises DNA or peptide nucleic acids (column 8, lines 36-62).

Gilmanshin et al teach a method, wherein the DNA sequence recognition units comprise any protein scaffold or synthetic molecular moiety capable of recognizing a specific DNA sequence (column 8, lines 36-62 and Column 17, lines 52-65).

Gilmanshin et al teach a method, wherein the stretching of the hybridized DNA complex in a random coil state to form a hybridized DNA complex in a substantially linear configuration is accomplished by using a mechanical means (Column 26, line 64 to Column 27, line 10).

Gilmanshin et al teach a method for single molecule identification of a target DNA molecule in a random coil state (Abstract, Column 26, lines 45 to column 27, line 10 and Figures 8-9) comprising the following steps:

a) stretching the hybridized DNA complex in a random coil state to form a hybridized DNA complex in a substantially linear configuration (Column 26, lines 45 to column 27, line 10 and Figures 8-9);

b) attaching an optically distinguishable material to a DNA sequence recognition unit (Column 25, lines 35-54);

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c) hybridizing the DNA sequence recognition unit to the target DNA molecule in a substantially linear configuration to form a hybridized DNA complex in a substantially linear configuration (Column 19, lines 42-63); and

d) detecting the optically distinguishable material in a sequential manner along the substantially linear hybridized DNA complex, thereby identifying the target DNA molecule (Examples 2-3 and Figure 9).

Gilmanshin et al does not teach a method of single molecule identification, wherein the optically distinguishable material has a size of about 0.05 micrometer or greater.

Cubicciotti teaches a method of single molecule identification, wherein the optically distinguishable material has a size of about 0.05 micrometer or greater (Column 246, line 65 to Column 247, line 53).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method of single molecule identification, wherein the optically distinguishable material has a size of about 0.05 micrometer or greater of Cubicciotti into the method for single molecule identification of a target DNA molecule in a random coil state of Gilmanshin et al., since Cubicciotti states, "For example, by varying the size, density and/or surface charge of the reporter conjugated to target molecules and nucleic acids comprising a random-sequence library, an affinity threshold or set point can be established to select an individual aptamer or group of aptamers with desired binding strength. The aptamer binding strength required to assemble two nanospheres (i.e., target-nanosphere and aptamer-

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nanosphere conjugates) and remain bound throughout selection, detection and isolation steps increases exponentially with particle diameter. Affinity set points spanning more than four orders of magnitude can be established using as reporters uniform latex nanospheres having particle diameters ranging from 10-300 nm (Column 247, lines 1-13). ” By employing scientific reasoning, an ordinary artisan would have combined and substituted a method of single molecule identification, wherein the optically distinguishable material has a size of about 0.05 micrometer or greater of Cubicciotti into the method for single molecule identification of a target DNA molecule in a random coil state of Gilmanishin et al. in order to improve the analysis of a single nucleic acid molecule detection. An ordinary practitioner would have been motivated to combine and substitute a method of single molecule identification, wherein the optically distinguishable material has a size of about 0.05 micrometer or greater of Cubicciotti into the method for single molecule identification of a target DNA molecule in a random coil state of Gilmanishin et al., in order to achieve the express advantages, as noted by Cubicciotti, of a novel invention by which varying the size, density and/or surface charge of the reporter conjugated to target molecules and nucleic acids comprising a random-sequence library, an affinity threshold or set point can be established to select an individual aptamer or group of aptamers with desired binding strength.

***Response to Amendment***

4. In response to amendment, previous 102 rejection has been withdrawn. However, a new 103(a) rejection has been included.

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***Response to Arguments***

5. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to



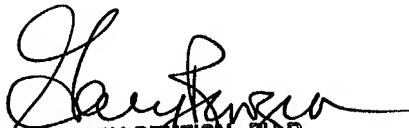
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Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

July 1, 2003

  
GARY BENZION, PH.D.  
SUPERVISORY PATENT EXAMINER  
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